#115



UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Takeda Chemical Industries, Ltd., and
Takeda Pharmaceuticals North America, Inc.,
Plaintiffs,
v.
Ranbaxy Laboratories, Ltd., and
Ranbaxy Pharmaceuticals, Inc.
Defendants.

Civil Action No.
03 CV 8250 (DLC) ← 4608

Takeda Chemical Industries, Ltd., and
Takeda Pharmaceuticals North America, Inc.,
Plaintiffs,
v.
Mylan Laboratories, Inc.,
Mylan Pharmaceuticals, Inc., and
UDL Laboratories, Inc.,
Defendants.

Civil Action No.
03 CV 8253 (DLC)

Takeda Chemical Industries, Ltd., and
Takeda Pharmaceuticals North America, Inc.,
Plaintiffs,
v.
Watson Pharmaceuticals, Inc.,
Watson Laboratories, Inc., Watson Pharma,
Inc. and Danbury Pharmacal, Inc.
Defendants.

Civil Action No.
03 CV 8254 (DLC)

Takeda Chemical Industries, Ltd., and
Takeda Pharmaceuticals North America, Inc.,
Plaintiffs,
v.
Alphapharm Pty. Ltd., and Genpharm, Inc.,
Defendants.

Civil Action No.
04 CV 1966 (DLC)



~~[PROPOSED]~~ **FINAL JUDGMENT**

This matter having come on for trial on the merits before the undersigned Hon. Denise Cote (without a jury), and having been tried to conclusion between January 17, 2006 and January 30, 2006, and upon all of the prior pleadings and proceedings herein, and upon and in accordance with the Court's Opinion and Order dated February 21, 2006, it is hereby ORDERED, ADJUDGED and DECREED as follows:

1. Defendants Alphapharm Pty. Ltd. and Genpharm, Inc. (collectively "Alphapharm") have failed to meet their burden of proving that U.S. Patent No. 4,687,777 ("'777 Patent") is invalid. The '777 Patent remains valid. All affirmative defenses and counterclaims asserted by Alphapharm with respect to the '777 Patent are hereby dismissed on the merits and with prejudice.

2. Defendants Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc. and UDL Laboratories, Inc. (collectively "Mylan") have failed to meet their burden of proving that the '777 Patent is unenforceable. The '777 Patent remains enforceable. All affirmative defenses and counterclaims asserted by Mylan with respect to the '777 Patent are hereby dismissed on the merits and with prejudice.

3. Alphapharm infringed claims 1, 2 and 5 of the '777 Patent by filing Abbreviated New Drug Application ("ANDA") No. 76-799 with the Food and Drug Administration ("FDA") including a certification under 505(j)(2(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355). Alphapharm would further infringe claims 1, 2 and 5 of the '777 Patent by making, using, offering to sell or selling within the United States or by importing into the United States pioglitazone hydrochloride tablets as described in their ANDA.

4. Mylan infringed claims 1, 2 and 5 of the '777 Patent by filing ANDA No. 76-801 with the FDA including a certification under 505(j)(2(A)(vii)(IV) of the Federal Food, Drug and

Cosmetic Act (21 U.S.C. § 355). Mylan would further infringe claims 1, 2 and 5 of the '777 Patent by making, using, offering to sell or selling within the United States or by importing into the United States pioglitazone hydrochloride tablets as described in their ANDA.

5. Defendants Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc. (collectively "Ranbaxy") filed ANDA No. 76-800 with the FDA. Ranbaxy did not challenge the validity or enforceability of the '777 Patent in their ANDA or in this action. Ranbaxy would infringe claims 1, 2 and 5 of the '777 Patent by making, using, offering to sell or selling within the United States or by importing into the United States pioglitazone hydrochloride tablets as described in their ANDA.

6. Defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Watson Pharma., Inc. and Danbury Pharmacal, Inc. (collectively "Watson") filed ANDA No. 76-798 with the FDA. Watson did not challenge the validity or enforceability of the '777 Patent in their ANDA or in this action. Watson would infringe claims 1, 2 and 5 of the '777 Patent by making, using, offering to sell or selling within the United States or by importing into the United States pioglitazone hydrochloride tablets as described in their ANDA.

7. Alphapharm, Mylan, ~~Ranbaxy and Watson~~, their officers, agents and employees, and all persons acting (directly or indirectly) in privity or concert with them, are permanently enjoined pursuant to 35 U.S.C. § 271(e)(4)(B) from making, using, offering to sell or selling within the United States and from importing into the United States pioglitazone hydrochloride tablets as described in ANDA Nos. 76-799 (Alphapharm), and 76-801 (Mylan), ~~76-800 (Ranbaxy) and 76-798 (Watson)~~ until the expiration date of the '777 Patent, as that date may be extended pursuant to law.

8. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA Nos. 76-799 (Alphapharm), 76-801 (Mylan), 76-800 (Ranbaxy) and 76-798 (Watson), or amendments thereof, shall be a date which is not earlier than the expiration date of the '777 Patent, January 17, 2011, as that date may be extended pursuant to law.

9. Plaintiffs Takeda Pharmaceutical Company, Ltd. (formerly Takeda Chemical Industries, Ltd.) and Takeda Pharmaceuticals North America, Inc. (collectively "Takeda") have requested that the Court determine that this case is exceptional with respect to Mylan's and Alphapharm's challenges to the '777 Patent, and have requested that the Court award their reasonable attorney fees pursuant to 35 U.S.C. § 285. Takeda may file a motion requesting such additional relief ~~within 20 days of the date hereof, and the Court will set a briefing schedule at that time~~ by March 31, 2006. Opposition is due April 21. Takeda's reply is due May 5, 2006, on which day Takeda shall supply two courtesy copies of all motion papers to Chambers.

SO ORDERED.

Dated: New York, New York
March __, 2006

DENISE COTE
United States District Judge

10. There being no just reason for delay, pursuant to Rule 54(b), Fed. R. Civ. P., the Clerk of Court shall enter final judgment for Takeda pursuant to paragraphs 1 through 8.

Denise Cote
March 10, 2006

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**PLEASE IMMEDIATELY SEND COPIES TO ALL COUNSEL**